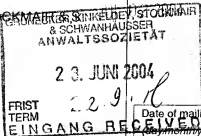


# PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION  
(PCT Rule 66)

Applicant's or agent's file reference  
PCT/US 03/20163

REPLY DUE

within 3 month(s)  
from the above date of mailing

International application No.  
PCT/US 03/20163

International filing date (day/month/year)  
26.06.2003

Priority date (day/month/year)  
27.06.2002

International Patent Classification (IPC) or both national classification and IPC  
A61K35/16

Applicant  
BERETTA, Roberto

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.
 

**When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

**How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

**Also:** For an additional opportunity to submit amendments, see Rule 66.4.  
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.  
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 27.10.2004

Name and mailing address of the international preliminary examining authority:



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## WRITTEN OPINION

International application No. PCT/US 03/20163

### I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

#### Description, Pages

1-53 as originally filed

#### Claims, Numbers

1 as originally filed

#### Drawings, Sheets

1/25-25/25 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

**WRITTEN OPINION**

International application No. PCT/US 03/20163

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)

Claims 1 (yes)

Inventive step (IS)

Claims 1 (no)

Industrial applicability (IA)

Claims 1 (yes)

2. Citations and explanations

**see separate sheet**

**WRITTEN OPINION  
SEPARATE SHEET**

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International application No. PCT/US 03/20163

1. Reference is made to the following documents:

D1: US 6368298

D2: US 5853600

2. Novelty

None of the cited documents disclose the claimed subject-matter. Claim 1 is therefore novel.

3. Inventive Step

D1 is considered to be the closest prior art. It refers to a method of preparing a solid-fibrin web, and differs from the claimed subject-matter in that the centrifugation step is not specified as being axially (see the whole document).

The problem to be solved by the present invention may therefore be regarded as defining an alternative method of preparing a solid-fibrin web from whole blood.

D2 discloses devices and methods for separating whole blood in its components, whereby axial centrifugation is used, allowing for a faster processing time and a smaller distance the blood components must travel (the whole document, especially column 2, lines 10-21). In the light of D2, it would be obvious to the expert in the field to apply the centrifugation method of D2 to the method of D1, in order to then arrive at the subject-matter of claim 1.

Claim 1 is therefore not considered to be inventive.